

Serial No. 09/696,635
Filed: October 25, 2000

Docket No. 55190US009

their invention. The Office Action asserts that the scope of claim 4 is unclear because it recites "EDTA" for the chelating agent ethylenediaminetetraacetic acid.

While Applicants disagree with the position stated in the Office Action, claim 4 has been amended to expedite prosecution. Claim 4 recites that the chelating agent is ethylenediaminetetraacetic acid. Support for the amendment may be found at page 5, line 23.

Claim 4, as amended, is in condition for allowance. Withdrawal of the rejection of claim 4 under 35 U.S.C. § 112, second paragraph is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 103

Claims 18-25 stand rejected as under 35 U.S.C. § 103(a) as being unpatentable over Andrews *et al.* (U.S. Pat. No. 5,460,833, issued October 24, 1995). The Office Action states that Andrews *et al.* discloses an antimicrobial composition comprising a fatty acid monoester in amounts within the instant claim, an enhancer in amounts within the instant claim, anionic surfactants, and a vehicle. The Office Action recognizes that Andrews *et al.* does not disclose a kit comprising the same known composition or an article of manufacture comprising the same known composition. However, the Office Action asserts that one having ordinary skill in the art at the time the invention was made would have been motivated to prepare a kit comprising the same known composition or an article of manufacture comprising the same known composition because preparation of a kit or an article of manufacture is considered well within the skill of the artisan and involved merely routine skill in the art. Applicants respectfully disagree with the position set forth in the Office Action.

Claim 18 recites a kit comprising a first container having a fatty acid monoester composition, said fatty acid monoester composition comprising a fatty acid monoester, a surfactant, and a vehicle; and a second container having an enhancer. Surprisingly, an antimicrobial formulation provided in this way (a "two-part" formulation) provides increased antimicrobial activity compared to an antimicrobial formulation of the same composition provided in a single container (a "one-part" formulation). The division of the antimicrobial formulation to form the kit recited in claim 18 involves more than routine skill in the art because the particular kit recited in claim 18 surprisingly provides improved antimicrobial activity compared to the antimicrobial formulation reported in Andrews *et al.*

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Table 3, runs 5-7, shows the results of testing the antimicrobial activity of a one-part formulation, Formulation 78A, comprising propylene glycol monocaprylate (PGMC8), lactic acid, an anionic surfactant (PAT 122A), sodium lauryl sulfate (NaLSO₄) and a nonionic surfactant (SPAN 20) in the ratios 14:20:8:2:2, respectively. Runs 8-10 test the antimicrobial activity of a two-part formulation including Formulation 37A (PGMC8, anionic surfactant, NaLSO₄, and a nonionic surfactant provided in a ratio of 14:8:2:2, respectively) to which 20 parts lactic acid, an enhancer, was added to provide the same components in the same ratios as provided in the one-part formulation, 78A. Table 3 shows that the one-part antimicrobial formulation provided an average of about a 5.49 decimal log reduction in colony forming units (CFUs). The two-part formulation provided an average of about a 6.54 decimal log reduction of CFUs. Thus, surprisingly, the two-part formulation, the formulation corresponding to that provided in the kit claim of claim 18, provided more than a 10-fold increase in antimicrobial activity compared to a one-part formulation having the same composition, i.e., the formulation corresponding to that provided in Andrews *et al.*

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Similar results are shown in Table 4, where the two-part formulation (run 24) provided a 6.46 decimal log reduction in CFUs, while the one-part formulation having the same composition provided an average of about a 5.14 decimal log reduction in CFUs. Thus, the two-part formulation, corresponding to the formulation provided in the kit of claim 18, provided more than a 1.3 decimal log reduction in CFUs, or about a 20-fold increase in antimicrobial activity compared to the one-part formulation, corresponding to the formulation provided in Andrews *et al.*

Even if, *arguendo*, one of skill in the art at the time the invention was made would have been motivated to prepare a kit comprising a known composition, as stated in the Office Action, one would not have been motivated to provide a kit in which the components are separated so that the two-part formulation provides increased antimicrobial activity compared to the known, one-part formulation. Moreover, neither Andrews *et al.* nor any other reference teaches or suggests how to separate the components of the formulation in order to obtain a 10-fold increase in antimicrobial activity. Therefore, there is no teaching or suggestion in Andrews *et al.* or any other reference that would have motivated one skilled in the art at the time the invention was made to prepare the kit of claim 18.

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Therefore, the kit of claim 18 is patentable over Andrews *et al.* and the rejection of claim 18 under 35 U.S.C. § 103(a) is improper. Claims 19-24 depended from claim 18. Claim 23 has been canceled. Therefore, Applicants submit that claims 19-22 and 24 are patentable for at least the reasons set forth above regarding the patentability of claim 18. Reconsideration and withdrawal of the rejection of claims 18-22 and 24 under 35 U.S.C. § 103(a) is kindly solicited.

Claim 25 recites an article of manufacture comprising, *inter alia*, an antimicrobial formulation and packaging material wherein the packaging material contains a label indicating that the formulation is ready to be applied to plants and plant parts to reduce levels of microbes. Andrews *et al.* is generally related to a product and process to reduce the microbial contamination of processed meat. Andrews *et al.* contains no teaching or suggestion of an article of manufacture as claimed in claim 25. In particular, Andrews *et al.* fails to teach or suggest packaging materials including a label. Thus, one of skill in the art would have had no motivation from Andrews *et al.* to construct an article of manufacture, according to claim 25, including an antimicrobial formulation and packaging material including a label.

Even if, *arguendo*, one of skill in the art would have been motivated at the time the invention was made to construct an article of manufacture including an antimicrobial formulation of Andrews *et al.* and packing materials including a label, no motivation existed to indicate that antimicrobial formulations could reduce the level of microbes on plants or plant parts. The surfaces of meats differ in physical and chemical properties from the surfaces of plants or plant parts. Thus, disclosure that certain antimicrobial formulations reduce microbial contamination of meats, such as is reported in Andrews *et al.*, does not teach or suggest that the same formulations can reduce levels of microbes on plants or plant parts. Consequently, one of skill in the art at the time the invention was made would have had no motivation to apply the antimicrobial formulations of Andrews *et al.* to plants or plant parts and, therefore, would have had no motivation to construct an article of manufacture including a label indicating the formulation was ready to be applied to plants or plant parts to reduce levels of microbes.

The article of manufacture of claim 25 is therefore patentable over Andrews *et al.* and the rejection of claim 25 under 35 U.S.C. § 103(a) is improper. Withdrawal of the rejection of claim 25 under 35 U.S.C. § 103(a) in light of Andrews *et al.* is kindly solicited.

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REJECTIONS UNDER 35 U.S.C. § 102

Claims 1-11 and 13-16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Andrews *et al.* (U.S. Pat. No. 5,460,833). Claims 1, 2 and 13-16 have been canceled. Claims 3-11 had been dependent, directly or indirectly, from claim 1, but have been amended to depend, directly or indirectly, from claim 18. Thus, claims 3-11 are in condition for allowance for at least the reasons set forth above regarding the patentability of claim 18.

CONCLUSION

In view of the amendments and remarks provided above, Applicants submit that all claims under consideration are in condition for allowance. Reconsideration and allowance of the claims is respectfully requested.

Respectfully submitted,

Registration Number	Telephone Number
43,643	651/733-1507
Date	
January 11, 2002.	

Signature
<i>Christopher D. Gram</i>
Print Name
Christopher D. Gram

3M Office of Intellectual Property Counsel
3M Innovative Properties Company
P.O. Box 33427
St. Paul, Minnesota 55133-3427
Facsimile: 651/736-3833

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MARKED-UP VERSION

3. (Amended) The kit [formulation] of claim 18 [1], wherein said enhancer is a chelating agent, an acid, or an alcohol.
4. (Amended) The kit [formulation] of claim 3, wherein said chelating agent is [EDTA] ethylenediaminetetraacetic acid or salts thereof.
5. (Amended) The kit [formulation] of claim 3, wherein said enhancer is an organic acid.
6. (Amended) The kit [formulation] of claim 5, wherein said organic acid is lactic, mandelic, succinic, tartaric, ascorbic, salicylic, benzoic, acetic, malic, or adipic acid.
7. (Amended) The kit [formulation] of claim 3, wherein said alcohol is ethanol or isopropanol.
8. (Amended) The kit [formulation] of claim 18 [1], wherein said two or more anionic surfactants are selected from the group consisting of acyl lactylate salts, dioctyl sulfosuccinate salts, lauryl sulfate salts, dodecylbenzene sulfonate salts, and salts of C8-C18 fatty acids.
9. (Amended) The kit [formulation] of claim 18 [1], said formulation comprising two anionic surfactants.
10. (Amended) The kit [formulation] of claim 18 [1], wherein said vehicle is water, propylene glycol, polyethylene glycol, glycerin, ethanol, isopropanol, or combinations thereof.
11. (Amended) The kit [formulation] of claim 18 [1], said formulation further comprising a flavorant.

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